

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
DAVID M. NEVILLE ET AL.	)	
	)	Group Art Unit:Unassigned
Serial No.: Continuation under 37 C.F.R. 1.53(b)	)	
of Serial No. 09/064,413 filed	)	
April 22, 1998	)	
	)	Examiner: Unassigned
Filed: April 22, 1998	)	
	)	
For: USE OF IMMUNOTOXINS TO INDUCE	)	
IMMUNE TOLERANCE TO	)	
PANCREATIC ISLET	)	
TRANSPLANTATION	)	

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION  
Assistant Commissioner for Patents  
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.  
Suite 1200, The Candler Building  
127 Peachtree Street, N.E.  
Atlanta, Georgia 30303-1811

March 16, 2001

Sir:

Prior to considering the continuation application filed herewith, please enter the following amendments:

IN THE SPECIFICATION

Please delete the sequence listing on pages 51-54 and renumber pages 55-57 to 51-53.  
Please replace the original sequence listing with the revised sequence listing, as attached.

IN THE CLAIMS

Please cancel without prejudice claims 9 and 11.

Please replace claims 1, 10, and 13 with the following amended claims as follows:

1. A method of treating diabetes in a subject, comprising
  - (a) administering to the diabetic subject an immunotoxin, thereby reducing the subject's T-cell population;
  - (b) administering deoxyspergualin to the subject; and
  - (c) administering to the subject pancreatic islet cells from a donor.
10. The method of claim 1, wherein the deoxyspergualin is administered beginning 0 to 24 hours prior to administration of the pancreatic islet cells to the recipient and continuing up to several weeks thereafter.
13. A method of inhibiting a rejection response of a recipient of a pancreatic islet transplant by inducing immune tolerance in the recipient, comprising administering an immunotoxin and deoxyspergualin during the peritransplant period, thereby transiently reducing the number of T-cell lymphocytes and promoting long-term survival of the transplant.

REMARKS

Claims 9 and 11 are cancelled herein without prejudice. Claims 1, 10, and 13 are amended herein to include the combined use of deoxyspergualin with immunotoxin and pancreatic islet cell transplant. A marked-up version of the amended claims is attached hereto as Appendix A. Applicants requested these same claim amendments in an Amendment Pursuant to 37 C.F.R. § 1.116 dated December 18, 2000, in the parent application. In an Advisory Action dated January 18, 2001, the Examiner in the parent application declined to enter the amendments.

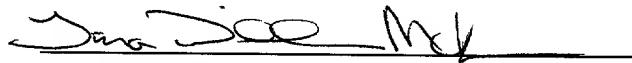
As amended, claims 1- 2, 4-8, and 12-13 are related to a method of treating diabetes or inhibiting a rejection response by administering an immunotoxin, such as UCHT-CRM-9, by performing a pancreatic islet cell transplantation, *and* administering deoxyspergualin to the subject. No new matter is believed to be added as support for the amendments can be found throughout the specification and in claims 9 and 11 as originally filed.

The Sequence Listing has been amended to comply with the requirements of 37 C.F.R. §§ 1.821-825. No new matter is believed to be added. A new computer readable form is provided on the attached diskette. The content of the computer readable form is the same as the enclosed paper copy.

Pursuant to the above amendments and remarks, consideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

A copy of the request for a one-month extension of time to maintain co-pendency and a check in the amount of \$710.00 for filing fee are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,




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CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, No. EL403505193US in an envelope addressed to: Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231, on the date shown below.

  
Everardo McFarlane

3/6/01  
Date

**Appendix A**  
**Marked-up Version of Amended Claims**

1. (Amended) A method of treating diabetes in a subject, comprising
- (a) administering to the diabetic subject an immunotoxin, thereby reducing the subject's T-cell population;
  - (b) administering deoxyspergualin to the subject; and
  - (c) administering to the subject pancreatic islet cells from a donor.--
10. (Amended) The method of claim 1[9], wherein the deoxyspergualin is [immunosuppressive agents are] administered beginning 0 to 24 hours prior to administration of the pancreatic islet cells to the recipient and continuing up to several weeks thereafter.
13. (Amended) A method of inhibiting a rejection response of a recipient of a pancreatic islet transplant by inducing immune tolerance in the recipient, comprising administering an immunotoxin and deoxyspergualin during the peritransplant period, thereby transiently reducing the number of T-cell lymphocytes and promoting long-term survival of the transplant.